

South Asia Biosafety Program

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Hear from leading scientists representing regulatory agencies, public sector research institutions, and the private sector at the

5th Annual South Asia Biosafety Conference

September 11-13, 2017 in Bangalore, India



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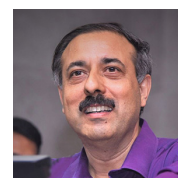
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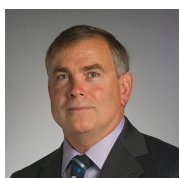
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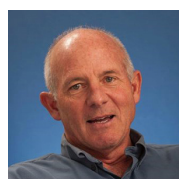
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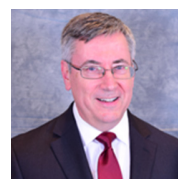
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Highlights from the Bangladesh Biosafety Regulatory Delegates Visit to the Philippines, Malaysia, and Singapore

Dr. Monzur Morshed Ahmed, Member, Biosafety Core Committee (BCC), Research Coordinator & Principal Scientific Officer, Bangladesh Council of Scientific and Industrial Research, Dhaka

A five-member delegation headed by Mr. Abdullah Al Mohsin Chowdhury, Additional Secretary (Development), Ministry of Environment and Forests, Government of Bangladesh visited the Philippines, Malaysia, and Singapore in July 2017 as part of the Implementation of National Biosafety Framework (INBF) project to learn about biosafety regulatory systems in these East Asian countries. The team members included Mr. Mohammed Solaiman Haider, Director (Planning), Department of Environment & Project Director, INBF Project; Mr. Monzur Morshed Ahmed, Research Coordinator (PSO), Bangladesh Council for Scientific and Industrial Research (BCSIR); Mr. Mohammad Golam Kibria, Deputy Secretary, Ministry of Environment and Forests; and Ms. Papia Sultana, Assistant Director, Department of Environment.

"The trip helped further understanding of biosafety systems, regulatory mechanisms, as well as monitoring and enforcement facilities in these countries for benchmarking with Bangladesh's systems."

Rice research. Additionally, a field trip to Bt corn fields in the rural areas of Tarlac took place, which involved interactions with the Bt corn farmers.

In the Philippines, the National Committee on Biosafety of the Philippines (NCBP) and Institutional Biosafety Committee (IBC) formulate policies and guidelines on biosafety, as well as contained trials, confined trials, open field trials, commercial use, and importation for direct use as food, feed or for processing. The Department of Health (DH) formulates environmental health impact assessment guidelines and evaluates environmental health, while the Department of Foreign Affairs (DFA) considers the country's biosafety interests at the international and national levels. The Department of Trade and Industry (DTI) oversees biosafety as related to IPR and consumer welfare, whereas the Department of Interior and Local



The tour was comprised of interactions with biosafety regulatory authorities, along with field and laboratory visits. The trip helped further understanding of biosafety systems, regulatory mechanisms, as well as monitoring and enforcement facilities in these countries for benchmarking with Bangladesh's systems.

THE PHILIPPINES

The tour began in the Philippines on July 5, with a visit to the Department of Agriculture. A bilateral meeting was held with Under Secretary Dr. S. Serrano, along with Mr. J. Estacio, Ma. L. Agbagala of the Department of Agriculture, Biotech Program (PIU); Dr. V. Mamaril and representatives of the Department of S&T and Departments of Health. Presentations on the Philippines Regulatory Framework, Executive Order (EO) 514, National Committee on Biosafety of the Philippines (NCBP), and joint department circulars were shared. The team also visited the facilities in Los Banos, including the Institute of Plant Breeding (IPB), to learn about development progress of the Bt eggplant contained trial, and the International Rice Research Institute (IRRI), to see the facilities for Golden

Government weighs biosafety decisions that may impact the autonomy of local governments.

Overall, biosafety regulatory systems here are well-coordinated between the various ministries, thanks in part to the establishment of the "Information Sharing and Biosafety Clearing House," a user-friendly information sharing system.

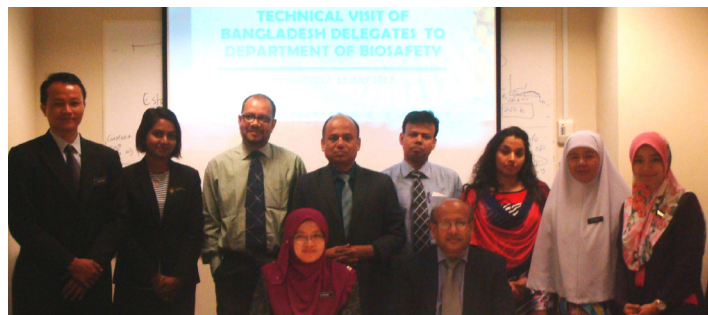
MALAYSIA

The Director General of the Department of Biosafety (DOB) and other relevant officials held bilateral meetings, presentations, and interactions with the Bangladesh team at its Putrajaya office on July 10 and 11. A briefing on sampling activities of GM products at Port Klang was given by a representative of the Malaysian Agriculture and Quarantine Inspection Services (MAQIS) and a briefing on GM food labelling regulations was given by a representative of the Ministry of Health (MOH).

In Malaysia, biosafety issues connected to GMOs are administered by the National Biosafety Board (NBB). NBB is an integrated governmental



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body comprising of the Ministry of Health, Ministry of Agriculture, Ministry of International Trade and Industry, and Ministry of Plantation Industries and Commodities. NBB is supported by the Department of Biosafety, under the Ministry of Natural Resources and Environment. Biosafety regulation in Malaysia takes its present form thanks to the Biosafety Act (2007), Biosafety Approval and Notification Regulations (2010), Food Act (1983), and other corresponding laws, guidelines, and regulations. GM product sampling activities in Port Klang are performed by the Malaysian Quarantine and Inspection Services (MAQIS) under the Ministry of Agriculture. Labeling and standardization of food derived from modern biotechnology is handled by the Food Safety and Quality Division under the Ministry of Health. A fully organized biosafety regulatory system prevails in Malaysia.

SINGAPORE

Bangladesh's delegates visited Singapore on July 13, and the team had face-to-face interactions with representatives of the Genetic Modification Advisory Committee (GMAC), Agri-Food & Veterinary Authority (AVA), and connected laboratory personnel. Following presentations and discussions, the team received a guided visit to the laboratories for GMO

detection and pesticide residue analysis. In Singapore, biosafety issues connected with GMOs are administered by GMAC, in conjunction with all the relevant ministries and departments.

SUMMARY & WAY FORWARD

The Philippines, Malaysia, and Singapore all have comparatively well-coordinated and organized biosafety regulatory systems. Biosafety stakeholder departments and organizations collaborate to perform biosafety activities as per the rules and regulations. However, biosafety awareness among the public is still low and requires adequate programs.

With the visited countries as benchmarks, it seems that biosafety regulation in Bangladesh needs much more attention in terms of operation and implementation. For GMO sample collection and detection of traceability, the experience of the Philippines, Malaysia, and Singapore could be useful. For effective biosafety operation and implementation in Bangladesh, the following points may be considered:

- the functionality of the NCB, BCC, and IBCs should be improved by holding regular meetings and activities, as well as through additional support in terms of technical manpower, logistics, and allocated funding;
- several scientific committees, such as those for health risk assessment, environmental risk assessment, food risk assessment etc., could be established to assist and guide the Biosafety Core Committee (BCC);
- a separate biosafety division should be created and staffed within the organizational structure of the Department of Environment; and
- border control and quarantine facilities should be strengthened in terms of handling GMOs and GM products.

INDIA

Phosphite: A Novel P Fertilizer for Weed Management and Pathogen Control in Rice Cultivation

Dr. M. K. Reddy, Dr. V. Mohan M. Achary, Dr. Varakumar Panditi, and Dr. Vijay Shri, Mrinalini Manna Crop Improvement Group, International Centre for Genetic Engineering and Biotechnology, New Delhi

Fertilizers and herbicides are vital for modern agriculture. The availability of orthophosphate (Pi) is a key determinant of crop productivity. The imminent danger of phosphate reserve depletion and multiple herbicide tolerance casts doubt on agricultural sustainability in the future.

Competition from weeds for this essential macronutrient further reduces its bio-availability. To compensate for low Pi use efficiency and address the weed hazard, excess Pi fertilizers and herbicides are routinely applied, resulting in increased production costs, soil degradation, and eutrophication. These outcomes necessitate the identification of a suitable alternate technology that can address the problems associated with the overuse of Pi-based fertilizers and herbicides in agriculture.

Phosphite (Phi), a reduced form of phosphorus, has been used as a fungicide and biostimulant in many agricultural crops, but its use as sole phosphorus (P) in agriculture has been limited because plants do not have machinery to metabolize it. However, there are certain bacteria found in nature that can thrive on Phi as the sole source of P. These microorganisms possess an enzyme called phosphite dehydrogenase (PtxD), which oxidizes Phi into Pi in the presence of Nicotinamide adenine dinucleotide (NAD) or Nicotinamide adenine dinucleotide phosphate (NADP) as a cofactor. The Phi-derived-Pi is further utilized by these microbes for various cellular activities. The PtxD protein of *Pseudomonas stutzeri* WM88 strain has been extensively studied and its ectopic expression in rice led to improved root growth, physiology and overall phenotype in addition to

normal yields in transgenic plants in the presence of Phi.

Phi has been found to behave as a translocative, non-selective, pre- and post-emergent herbicide. The adoption of Phi-based farming can be an important strategy for realizing sustainable agriculture. This technology has the potential to prevent overuse of the limited Pi reserve and is environmentally sound. The Phi fertilizer use efficiency is close to 100% because of its high solubility and reduced reactivity with soil components and non-utilization by most soil bacteria. Transgenic plants overexpressing ptxD gene are able to metabolize Phi as a source of P. This transgenic technology together with Phi fertilizer requires only 30% of the current P usage for optimum crop productivity and reduces production costs.

Because non-transgenic plants are unable to metabolize Phi, it acts as a very effective pre- and post-emergent systemic herbicide. Phi-based weed management technology is environmentally more friendly than current weed management practices. The application of Phi protects crops against several devastating fungal and bacterial pathogens since Phi is the active component of fungicides and bactericides. Phi is minimally or non-toxic to humans and other higher animals and is degraded by selective soil microbes, with no carryover effect on subsequent crop rotation, thus benefiting the environment and human health. Additionally, Phi is an excellent bio-stimulant for many horticultural and vegetable plants. Thus, Phi based fertilization can handle multiple problems that modern agriculture faces and at the same time its usage can be proven economically and environmentally beneficial.

"The adoption of Phi-based farming can be an important strategy for realizing sustainable agriculture."

Development of Herbicide Tolerant Transgenic Rice Plants for Weed Management in Modern Indian Farming Systems

Dr. M. K. Reddy, Dr. V. Mohan M. Achary, Dr. Vijay Shri, Dr. Varakumar Panditi, and Dr. Bhabesh Borphukan, Crop Improvement Group, International Centre for Genetic Engineering and Biotechnology, New Delhi

Weeds are the most serious biological constraint to upland rice production. Traditional weed control over large areas is not feasible because of constraints in labor supply, higher monetary costs, and difficulty in distinguishing weeds from crop plants at early stages. Weeds not only compete with crops for water, nutrients, and light but also function as alternate hosts for many disease-causing pathogens leading to heavy losses in yields. Chemical methods of weed control is the most promising method for tackling a variety of weeds.

Synthetic herbicides target certain crucial enzymes that are essential for cellular metabolism in plants, the popular among which are 5-enolpyruvylshikimate-3-phosphate (EPSP) and acetolactate synthase (ALS). The genes encoding these enzymes are well-conserved in plants, fungi, and microbes and are responsible for the synthesis of aromatic and branched chain amino acids respectively. Glyphosate (Roundup), the most widely used broad spectrum, post-emergence herbicide inhibits EPSP synthase. Sulfonylureas and their derivatives are used as pre-emergence herbicides that inhibit ALS.

Sustainable use of chemical herbicides essentially involves development of herbicide tolerant transgenic crop plants that are not affected while herbicides are non-selectively applied all over the crop fields. Glyphosate resistant transgenic crops have been rapidly adopted in more than 80% of cultivable land for soybean, maize, cotton, canola, and sugar beet cultivation in the United States, as well as many other developed countries. Further, more than 50 ALS inhibitors have been identified and approved for commercial use as herbicides.

“This herbicide tolerant rice plant shall be immensely beneficial for integrated weed management during upland rice cultivation by controlling a large number of weed species, thereby reducing the gap between rice production and consumption in India.”

The sources of herbicide tolerant transgenes are invariably certain microorganisms, and their use for developing transgenic plants has been the subject of ethical controversy in Indian agricultural biotechnology. To address this, we have developed an alternative cisgenics approach for inducing herbicide tolerance in rice plants. We have introduced multisite-compensation mutations in the rice EPSPS and ALS gene for herbicide tolerance. Without introducing any heterologous genes, we have successfully developed cisgenic rice plants resistant to two broad-

spectrum, non-selective, and systemic herbicides, namely sulfonylurea for pre-emergent application and glyphosate for post-emergent application. We followed a herbicide target site modification strategy to develop herbicide tolerance by introducing multisite-compensating mutations in rice EPSP synthase (OsEPSPS) and acetolactate

synthase (OsALS) genes that interfere with herbicide binding but retain their normal functioning in the presence herbicide. The cisgenic rice plants harboring overexpressed mutant EPSPS or ALS genes showed normal growth and development, as well as high levels of glyphosate and sulfonylureas resistance in the field, without any injury and fitness cost.

This herbicide tolerant rice plant shall be immensely beneficial for integrated weed management during upland rice cultivation by controlling a large number of weed species, thereby reducing the gap between rice production and consumption in India. Furthermore, the novel CRISPR/Cas9 mediated in vivo gene editing technology can be employed as a very important tool for future crop improvement programs by cisgenics approach.



Phase I of GE Food and Feed Safety Assessment Training Completed in Indonesia

Dr. Xianglu Han, Scientific Program Manager, ILSI Research Foundation, United States



On August 1-3, 2017, a three-day technical training program was conducted in Bogor, Indonesia, organized by the ILSI Research Foundation in cooperation with the Indonesian National Agency for Food and Drug Control (BPOM) and the Indonesian Center for Animal Research and Development (ICARD). This activity provided an opportunity for participants to engage in practical exercises highlighting the fundamental concepts employed in food and feed safety assessments of genetically engineered (GE) crops.

Twenty-three participants from both the Indonesian Food Safety Technical Team and the Feed Safety Technical Team attended the training held at the Harris Hotel. The training was supported by expert faculty from the United States and the Philippines, including Dr. Donald MacKenzie, International Rice Research Institute, Dr. Florida Carino, University of the Philippines, Dr. Bryan Delaney, DuPont Pioneer, Dr. Andrew Roberts and Dr. Xianglu Han, ILSI Research Foundation. The workshop introduced important concepts and components for food and feed safety assessment, including problem formulation, toxicity, composition, and allergenicity assessment, as well as molecular characterization. The structure of the



program involved more than just lectures and included the opportunity for participants to work through practical exercises in groups. These exercises focused on the ability to identify and use available information resources associated with food and feed safety assessments as well as providing an opportunity to consider topics in more detail.

Building off the Phase I program, the ILSI Research Foundation is organizing a five-day Phase II training program at the Stine Haskell Research Facility in Wilmington, DE, USA, in November, which will include the opportunity to observe how food and feed safety assessment data is collected in the laboratory.

This work is supported by a grant from the United States Department of Agriculture, Emerging Markets Program.

To learn more about the ILSI Research Foundation's program on GE food and feed safety, visit: www.ilsirf.org/what-we-do/ge-food-feed



100% of survey responders who participated in the workshop found it useful to their position and would recommend it to a colleague. Read more about their impressions:

- "As a member of the feed safety assessment technical team, the workshop was very useful for gaining detail information about food and feed safety assessment."
- "Since I am a Technical Manager of Biotechnology Laboratory who is responsible for GMF detection, this training course bridges my knowledge on safety assessment (pre market control) and post market control (GMF detection)."
- "Excellent quality overall."
- "The topic regarding the database of GM crop provided from the ILSI Research Foundation is very useful in any aspects. This has broadened my perspective regarding the list of useful databases, especially on the assessment of GM crop in general."
- "All aspects of workshop were valuable and useful in strengthening our capability in assessing safety of foods and feeds derived from GE crop. Applying problem formulation to the safety assessment of GE foods and feeds is most valuable for me."

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Series of Consultation Workshops on Mainstreaming of Biodiversity: National Biodiversity Action Plan, National Biodiversity Targets and India's Sixth National Report to Convention on Biological Diversity	Ministry of Environment, Forest and Climate Change (MoEFCC), United Nations Development Programme, National Biodiversity Authority and Biotech Consortium India Limited (BCIL)	July- October, 2017 Chandigarh, Guwahati, Lucknow, Ahmedabad, Hyderabad and Delhi	www.bcil.nic.in
International Symposium on Sugarcane Research Co 205: 100 Years and Beyond	ICAR-Sugarcane Breeding Institute, Tamil Nadu Agricultural University, The South Indian Sugar Mills Association and Society for Sugarcane Research and Development Coimbatore	September 17-20, 2017 Coimbatore	http://bit.ly/ICAR_Sep2017
International Conference and Expo on Biotechnology and Healthcare	Centre for Good Governance and Prof. Jayashankar Telangana State Agricultural University (PJTSAU)	October 26-27, 2017 Hyderabad	http://biotechconference.org
Training Programme on "Use of biotechnological and conventional tools in understanding virus-host"	ICAR- Indian Agricultural Research Institute	November 7-27, 2017 New Delhi	http://bit.ly/2wavDwz
TERI-ITEC Courses 2017-18: Course IV - Applications of Biotechnology and its Regulation	The Energy and Resources Institute	November 20- December 8, 2017 Gual Pahari, Gurgaon	www.teriin.org/events/upcoming
Fostering Innovations in Fisheries and Aquaculture Focus on Sustainability and Safety	ICAR - Central Institute of Fisheries Technology and Asian Fisheries Society Indian Branch (AFSIB)	November 21-24, 2017 Bengaluru	http://bit.ly/2wqW3g7
IPSAACON2017 XXXIV Annual Conference of the Indian Poultry Science Association	Indian Poultry Science Association ICAR-National Institute of Animal Nutrition and ICAR-National Institute of Animal Nutrition and Physiology	November 28-30, 2017 Bengaluru	http://bit.ly/2wrmNwS
INTERNATIONAL			
Asian Subregional Workshop on Strengthening Capacities for the Integrated Implementation of the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and the Convention on Biological Diversity	CBD Secretariat	November 6-10, 2017 Kuala Lumpur, Malaysia	www.cbd.int/meetings



SOUTH ASIA
BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international developmental program implemented in India and Bangladesh with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.



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Research
Foundation



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FROM THE AMERICAN PEOPLE



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